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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/237,605	01/25/1999	RICHARD J. LAZZARA	IMPI.035-1	7280

30223 7590 07/16/2002

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EXAMINER	
PREBILIC, PAUL B	
ART UNIT	PAPER NUMBER

3738

DATE MAILED: 07/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/237,605	LAZZARA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Paul B. Prebilic	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 April 2002.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 11-25,27-33,35-49 and 51-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 11-25,27-33,35-49 and 51-56 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                              | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>35,36,40</u> | 6) <input type="checkbox"/> Other: _____                                    |

The PTO-1449 form copies supplied with this Office action have had some citations struck therefrom. The US patents have been cited more than once and the foreign language references have no translation of at least the relevant portions thereof as required.

***Claim Rejections - 35 USC 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-21, 27-33, 35-49, and 51-56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The terminology "substantially" or "substantially removed" to describe the degree to which the native oxide layer is removed or the uniformity of the roughness lacks original support and/or there is no guidance as to its affect on the metes and bounds of the claim language. Since there is no guidance in the original specification, it appears that even a bulk etched metal implant surface would be substantially uniform in roughness and substantially free of the native oxide layer. Moreover, "substantially" is a broad term. *In re Nehrenberg*, 126 USPQ 383 (CCPA 1960) and see MPEP 2173.05(b) which is incorporated herein by reference. The specification fails to provide some standard for measuring that degree. Therefore, one of ordinary skill would not know

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what degree of roughness or native oxide layer would fall within the claim scope and what would not. The controlling case law appears to be that of *In re Mattison*, 184 USPQ 383 (CCPA 1960). It states:

We are not persuaded by the board's reasoning that one skilled in the art would not be able to determine the scope of the claimed invention in terms of a specified percentage value. General guidelines are disclosed for a proper choice of the substituent Ep together with a representative number of examples. (emphasis added here)

The Board of Appeals was reversed because there were general guidelines as to what constituted a substantial increase. This is not the situation here where there are no guidelines in the specification, and the prior art does not give one a clear picture as to what constitutes a substantially uniform roughness or a surface substantially free of native oxide and what does not. This is a critical and defining limitation of the claim and it must be clear as to what falls within its scope.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-21, 27-33, 35-49, and 51-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The scope of the claims is indefinite because of the ambiguity presented by the □substantially□ terminology discussed in the 35 USC 112, first paragraph rejection.

#### ***Claim Rejections Based Upon Prior Art***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-16, 22-25, 27-33, 35-49, and 54-56 are rejected under 35 U.S.C. 102(b) as anticipated by Krueger (US 4,826,434) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Krueger (US 4,826,434) alone. Krueger anticipates the claim language wherein Krueger teaches a threaded surface intermediate product which has been etched to remove impurities; see the whole document, especially Figure 3 and Col. 3, line 38 to Col. 4, line 7. The Examiner asserts that at least one of the intermediate product (Col. 3, lines 50-56) and the final etched product would have their native oxide layers removed and would have irregularities of less than 10 microns approaching 0 microns; he therefore burden the Applicant to show otherwise. It is noted that the present claim language is now written in product-by-process format with two steps of treatment. Therefore, the Examiner is under a lesser burden of proof to show that these peculiar limitations are present in the prior art. The Examiner takes the position that the two step process would result in the same intermediate or final product due to the fact that it merely removes the oxide layer and smoothes the outer surface. Consequently, the Examiner hereby asserts that the Krueger appears to be identical to

the device set forth in the present claims; MPEP 2113 is hereby incorporated herein by reference thereto.

Alternatively, it is not clear that the intermediate product surface has a native oxide layer removed to the extent required, but the Examiner posits that the etching process, which increases the surface area by two, would obviously remove the native oxide layer to the extent claimed and the Examiner hereby burdens Applicant to show that the product disclosed by Krueger does not meet or obviate the claimed invention. Since the Office does not have facilities to test the prior art against the Applicant's invention, it is the Examiner's prerogative to burden the Applicant to do the same when certain physical properties appear to be present in the prior art even though not explicitly taught thereby. In addition, since product-by-process claim language is now used, the Examiner asserts, under this interpretation, that the presently claimed invention is at least substantially identical to that set forth in Krueger.

With regard to claims 12, 25, 28, 38, 46, 47, and 54-56, the Examiner posits that since the same type of etching process is used to form irregularities on the surface of the same material as claimed that the surface irregularities of Krueger would inherently be the same as those set forth in the claims; i.e. substantially cone-shaped and/or spaced about the prescribed distance.

With regard to claims 13 and 36, the Examiner posits that the claimed process steps result in the same invention such that the claimed invention is at least clearly obvious in view thereof. The Examiner is also under a lesser burden to show that

process limitations in product claims are met; see MPEP 2113, which is incorporated into this Office action by reference thereto.

Claims 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krueger as applied to claims 11-16, 22-25, and 27-49 above, and further in view of Wagner et al (US 5,989,027). Krueger at least obviates the claim language as set forth in the above rejection but fails to teach both a roughened region and an unroughened or other region as required by the claims. Wagner et al teaches that it was known in the art to have different regions of roughness; see the entire document. Hence, it is the Examiner's position that it would have been obvious to have a smoother head portion in the Krueger invention for the same reasons that Wagner et al has the same.

Claims 11-16, 22, 24, 25, 27-33, 36-49, and 54-56 are rejected under 35 U.S.C. 102(b) as anticipated by Schulte et al (article published 1992) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schulte et al (article published 1992). Schulte et al anticipates the claim language wherein the irregularities are 2 to 5 microns high and substantially uniform; see the whole document, especially Figure 14 and its caption. The Examiner posits that the oxide layer, if any, would be substantially removed to the extent required.

Alternatively, since the claims are set forth in the peculiar product-by-process format, it is not clear whether the Schulte et al device is identical or only substantially identical as to that claimed. However, the Examiner posits that the Schulte et al device at least clearly obviates the claimed invention because it appears to be at least

substantially identical thereto; see MPEP 2113 which is incorporated herein by reference thereto.

***Response to Arguments***

Applicant's arguments filed April 29, 2002 have been considered but they are not persuasive.

In response to the Applicants' argument that the "substantially" objection should be withdrawn, it is the Examiner's position that since there is a lack of guidance in this regard, it would not be proper to withdraw the rejection. This is due to the fact that the case law is relatively clear as to what is required and the present disclosure falls short of that standard.

In response to the argument that examples are given Examples 1 and 2 as to what constitutes substantial removal of the oxide layer and what constitutes substantially uniform irregularities, the Examiner posits that the substantial terminology is not used therein. It is noted that even Figure 3 of the parent case (US 5,876,453) has substantial removal of native oxide and a substantially uniform surface; see Example 2 thereof. In fact, the disclosure thereof admits that the areas where oxides are not removed have a uniformly irregular surface. For this reason, the Examiner posits that Figure 3 thereof falls within the meaning of substantially uniform irregularities with substantially all the oxide layer removed.

Applicants argue that the teachings of Krueger are vague and they cannot see suggestion of the claimed invention; i.e. the reason Krueger etches his surface, they argue, is for a different reason and purpose. However, it is well established that

anticipation is based upon a structure-to-structure comparison with the prior art. Since Krueger reasonably appears to have the same or similar structure as that set forth in the present claim language, the Examiner posits that the present claims are clearly unpatentable thereover. Moreover, the Examiner is under a lesser burden of proof when the claims are written in a product-by-process format because of their peculiar nature; see MPEP 2113.

As to the argument that it is not clear that Krueger has the claimed features of surface oxidation and roughness, the Examiner contends that the claim language is quite broad such that even Krueger's amount of detail anticipates or at least renders it obvious. Again, the claims must be viewed as a description of a product not by what steps they set forth. The method steps merely indicate what the final form of the invention might be.

Applicant argues that Krueger is vague such that one cannot determine what to compare to the present invention. In response, the Examiner suggests duplicating Krueger by etching a titanium surface with mineral acid so that the etch ratio results which is greater than 2; see column 3, line 65 to column 4, line 7. Having done this procedure, test the native oxide layer and examine the irregularities. It is noted, however, that the "substantially" language casts doubt into the scope of the claims so this terminology would have to be removed.

In response to the argument that Krueger does not clearly remove the oxide layer, the Examiner posits that Krueger's process normally removes the entire surface with all the impurities; see column 3, lines 53-56 which is incorporated herein by

reference thereto. Therefore, the Examiner reasons that most if not all of the oxide layer is inherently removed since the entire outer layer of material is removed.

In response to the argument that Krueger is non-enabling, the Examiner asserts that Applicants have fallen fall short of their burden in showing this. For this reason, the arguments have been considered unpersuasive.

Next, Applicants argue that Schulte is also vague and they cannot determine what is disclosed. In response, the Examiner posits that Schulte is sufficiently clear such that one can make a determination as to what is disclosed thereby. In particular, the claims of the present application are broadly recited with "substantially" and in product-by-process format such that they are read on by what is disclosed by Schulte. It appears that Applicants are reading more into the claims than is actually there.

The 37 CFR 1.132 declaration by Porter is considered to be deficient for the following reasons:

(1). It is not clear that the claimed invention was used in the devices for sale. Therefore, there is no clear nexus of the claimed invention to the commercial success claimed.

(2). The sales data provided is for relative amounts of the two types of implants sold without any actual sales numbers so it is hard to tell whether the overall sales dropped and the high percentages for the Osteotite was for a lower sales volume.

(3). The commercial success was not shown to be due to the claimed features and could have been due to heavy promotion of advertising, shift in advertising, unequal availabilities, or other business events extraneous to the merits of the claimed invention.

(4) There was not side-by-side comparison of the like products to the allegedly claimed invention so it is difficult to tell whether a true comparison of the two was made.

(5). The affidavit was executed by an employee of the same company so it is not a disinterested third party.

(6). The affidavit does not compare the closest prior art to the claimed invention.

(7) Paragons brochure (published 10/97) contradicts Applicants' arguments as to superiority of it to the competitors and it suggests that aggressive marketing was used instead.

### ***Conclusion***

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned problem is corrected.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9301.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.

  
Paul Prebilic  
Primary Examiner  
Art Unit 3738